REMARKS

The Office Action

Claims 15-38 are pending and examined in the present Office Action. Claims 15-38 are rejected under 35 U.S.C. § 103(a). Applicant addresses this rejection below.

Claim amendments

By the present amendments, claims 17-20 and 38 have been cancelled. Claim 15 has been amended to recite that the drug to be administered is ramipril. Claims 16 and 21-26 have been amended to delete the reference to the "inhibitor" since claim 15 was amended. Claims 22-24 have been amended to substitute said "drug" for "ramipril" since claim 15 was amended. Support for the amendments is found throughout the specification and the pending claims. For example, support for amended claim 15 can be found on page 7, lines 11 and 12. No new matter has been added by these amendments.

Rejection under 35 U.S.C. § 103(a)

Claims 15 to 38 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Chase et al. (*Ann. Ophthalmol.* 25:284-289 (1993); hereafter "Chase"). Applicant addresses this rejection by amendment with the following remarks.

M.P.E.P. § 2142 states:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references

themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991).

Applicant asserts that this standard for obviousness has not been met for the rejected claims as presently amended as Chase does not teach or suggest all of the limitations of the claimed invention. As amended, Claim 15, from which all pending claims depend, reads:

> "A method for maintaining or improving the visual acuity and the field of vision in a patient in need of such treatment, said method comprising:
> administering a drug comprising ramipril, wherein said drug maintains or improves visual acuity and the field of vision" (emphasis added).

Chase is directed to the use of captopril to treat retinal damage in young normotensive subjects with Type I diabetes. The Examiner states that the cited reference teaches the applicant's instant invention because captopril improved the eye grade of two subjects, thus improving the visual acuity of the subjects. Applicant respectfully disagrees.

Applicant asserts that Chase does not teach or suggest that improvements in visual acuity can be achieved using ramipril, and therefore, that the instant invention and the cited prior art disclosure are directed to the treatment of two entirely different conditions of the eye. This distinction is evidenced by the classification system used to evaluate the

treatments disclosed in the present specification and in Chase. Chase concerns the improvement and/or worsening of retinal changes using "retinal grades." The Examiner purports that visual acuity is connected to retinal grades, as defined in the cited reference. However, the term "retinal grades" is not related to visual acuity. Rather, it relates to degrees of diabetic retinopathy. This point is made clear in Chase, on page 286, left column, third paragraph, wherein retinal grades are defined by the "Airlie House" classification system:

> "Grading of retinal changes was done using the modified Airlie House system in which Grade 1 indicates no abnormalities, Grade 2 identifies microaneurysms only, Grades 3 and 4 represent intermediate stages of background retinopathy, and Grades 5 and 6 represent preproliferative and proliferative retinopathy, respectively."

By contrast, visual acuity grades are defined by a completely different classification system, using 10 grades that are determined by the ability of a person to read an eye chart with letters at a certain distance. More specifically, "visual acuity" is defined as "sharpness of vision, especially as tested with a Snellen chart. Normal visual acuity based on the Snellen chart is 20/20" (The American Heritage Stedman's Medical Dictionary). Thus, visual acuity is directed to sharpness of vision, whereas retinal grades relate to physiological abnormalities of the retina. This distinction clearly distinguishes the instant invention from the cited prior art reference as the two disclosures are directed to two different treatments of the eye.

Applicant notes that the claims have been narrowed to a method for maintaining or

improving visual acuity and the field of vision, said method comprising ramipril administration. Chase does not contain any suggestion or motivation that would lead the skilled person to use ramipril for maintaining or improving the visual acuity and the field of vision in a patient in need of such treatment. The Examiner has acknowledged that the instant invention differs from the cited reference in that the cited reference does not teach the use of ramipril, but asserts that one skilled in the art would have assumed that Chase states that all angiotensin-converting enzyme inhibitors, including ramipril and ramiprilat, are effective to improve visual acuity in the absence of evidence to the contrary. Applicant respectfully disagrees. As noted above, Chase is solely directed to the use of captopril to treat retinal damage in young normotensive subjects with Type I diabetes, whereas the instant invention relates to a method for maintaining or improving the visual acuity and the field of vision in a patient. Applicant asserts that captopril and ramipril are structurally different drugs. Chase does not disclose or even suggest using ramipril to affect visual acuity, much less retinal damage in normotensive subjects.

Applicant also asserts that the present invention demonstrates dramatic improvements in visual acuity and in the field of vision. For example, on page 9, lines 19 to 21, visual acuity in a patient has increased from 3/10 to 10/10 (left eye) and from 6/10 to 8/10 (right eye). This impressive increase in visual acuity and in the field of vision can only be deemed as an unexpected result, not demonstrated in the prior art.

For the reasons stated above, Chase cannot and does not support a *prima facie* case

of obviousness for the rejected claims. The rejection of these claims under § 103 may be withdrawn.

CONCLUSION

Applicant submits that the claims are now in condition for allowance, and such action is respectfully requested. Enclosed are a petition to extend the period for replying for one month, to and including October 22, 2004, and a check for $55.00 for the required petition fee. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: October 22, 2004

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